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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,070	07/18/2001	Dachuan Yang	S63.2-9826	7520

490 7590 10/23/2002

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

PHANIJPHAND, GWEN G

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/908,070

Applicant(s)

YANG ET AL.

Examiner

Gwen Phanijphand

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 U.S.C. 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-18 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,254,634 to Anderson et al.

Regarding claims 1, 15, and 31, Anderson et al. disclose in the Abstract preparing a mixture of a hydrophilic fluorescing agent and hydrophobic lubricant (col. 8, ll. 58-67 and col. 9) and applying the mixture to the surface of a medical device (col. 10, ll. 57-65) to form a coating capable of exhibiting fluorescence (col. 4, ll. 7-17). Regarding subjecting the surface of the device to a source of energy capable of inducing a fluorescent emission, it is inherent that when a coating containing fluorescein (col. 9, ll. 62-64) is subjected to an energy source, such as light, this source will induce the inherent fluorescent quality of the compound.

Regarding claims 2 and 16, Anderson et al. disclose observing the fluorescent emission to determine the location and uniformity of the lubricant. Anderson discloses fluorescein as a compound that can be used in the coating (col. 9, ll. 62-64). It is inherent that a lubricant coat containing fluorescein would emit fluorescence and could determine the location and uniformity of the lubricant.

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Regarding claims 3, 4, and 36-38, Anderson et al. disclose the fluorescing agent being fluorescein (col. 8, ll. 58-67 and col. 9, ll. 7-18, 62-64) or mixture thereof.

Regarding claims 5, 6, 7, 34, and 35, Anderson et al. disclose hydrophobic lubricant being a silicone based lubricant, being polydimethylsiloxane, and polydimethylsiloxane being utilized in combination with a cross-linkable silicone (col. 5, 41-64).

Regarding claims 8-11, and 32, Anderson et al. disclose a mixture further comprising a surfactant (col. 5, ll. 49-64; e.g. polydimethylsiloxane as listed on page 13 of the specification) being biocompatible, ionic and in an ethylene oxide/propylene oxide block copolymer (col. 5, ll. 55-64).

Regarding claims 12-14, Anderson et al. disclose a mixture prepared using a cosolvent blend, comprising at least one alcohol being isopropanol and at least one straight chain hydrocarbon (col. 5, ll. 42-65; col. 6, ll. 12-23).

Regarding claims 17 and 18, Anderson et al. disclose a medical device being intraluminal and a catheter (col. 10, ll. 56-65).

Regarding claim 33, Anderson et al. disclose a coating prepared by mixing the hydrophobic lubricious compound and the hydrophilic fluorescing agent (Abstract; col. 8, ll. 58-67; col. 9) in a cosolvent blend (col. 5, ll. 42-65; col. 6, ll. 12-23).

### ***Claim Rejections - 35 U.S.C. 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,254,634 B1 to Anderson et al.

Regarding claims 19-23, Anderson et al disclose a lubricious coating comprising a fluorescent dye (Abstract; col. 8, ll. 58-67; col. 9) and a method for determining the presence of a lubricious coating. The method of subjecting energy to induce the fluorescent quality of a compound is inherent to a coating containing the fluorescent compound, fluorescein (col. 9, ll. 62-64). Anderson et al. further disclose a catheter (col. 10, l. 58) and a stent as coatable devices, but however, do not disclose a stent retaining sleeve. It is well known that catheters are shaped and designed for different surgical purposes, and a catheter used to deliver a stent would have a sleeve to protect the stent until the stent has reached the location for implantation. It would have been well known and obvious to one having ordinary skill in the art at the time of the invention to include a stent sleeve on the catheter. The sleeve is advantageous because it provides a sterile delivery of the stent while also protecting the stent from being damaged during transit through the body.

Regarding claim 24, Anderson et al. disclose the lubricious coating comprising either a hydrophilic lubricant or a hydrophobic lubricant (col. 8, ll. 58-67 and col. 9, ll. 7-18, 62-64).

Regarding claims 25 and 26, Anderson et al. disclose the lubricious lubricant being polydimethylsiloxane and a crosslinkable material (col. 5, 41-64).

Regarding claim 27, Anderson et al. disclose the fluorescent dye being hydrophilic (col. 9, ll. 7-18, 62-64)

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Regarding claims 28 and 29, Anderson et al. disclose a fluorescing agent being fluorescein, rhodamine, triarylmethane, derivative thereof, or mixture thereof (col. 8, ll. 58-67 and col. 9, ll. 7-18, 62-64).

Regarding claim 30, Anderson et al. lubricant being a hydrogel (col. 8, ll. 58-67 and col. 9).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,447,501 to Solar et al.  
U.S. Patent No. 5,858,746 to Hubbell et al.  
U.S. Patent No. 5,670,097 to Duan et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845.


The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP  
October 18, 2002

Gwen Phanijphand  
Patent Examiner  
Art Unit 3731

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
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